UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

PAUL GEORGE, individually and on behalf of all others similarly situated in Missouri, Plaintiff, vs. BLUE DIAMOND GROWERS, Defendant.	Case No. 4:15-cv-00962-CEJ

PLAINTIFF'S MOTION TO RE-OPEN CASE AND TO LIFT THE STAY

Plaintiff Paul George ("Plaintiff") submits this Motion to Re-open Plaintiff's case and to Lift the Stay in accordance with this Court's Orders, dated April 14, 2016 (Doc. 30) and April 21, 2016 (Doc. 31), which directed that this case remain stayed (Doc. 30) and administratively closed (Doc. 31) pending the U.S. Food and Drug Administration's regulatory process regarding the terms "evaporated cane juice" ("ECJ") and "natural." A lift of the stay and re-opening of the case is appropriate because (1) the FDA has provided guidance regarding the term ECJ, which directly impacts this case; and (2) in opening a comment period for the term "natural," the FDA has not indicated when, if at all, it will issue guidance regarding the use of the term "natural." For 23 years the FDA has considered the term "natural" to mean that nothing artificial or synthetic is added to a food. And, it is likely that the FDA will not provide additional guidance regarding the term "natural" for several years, if at all. It would prejudice this case to continue to wait for such guidance, which may not be forthcoming.

INTRODUCTION AND PROCEDURAL BACKGROUND

On April 14, 2016, this Court ordered that the case be stayed pending the FDA's ongoing examination of the use of the terms ECJ and "natural." (Order, Doc. 30, April 14, 2016). In its April 21, 2016, Order, this Court administratively closed the case and advised the parties to move to open the case when the FDA had issued additional guidance regarding the use of the terms ECJ and natural. On May 25, 2016, the FDA issued additional guidance regarding the use of the term ECJ. Between November 12, 2015, and May 10, 2016, the FDA accepted public comment on the use of the term "natural" in the labeling of human food products, but it is not clear that the FDA intends to offer additional guidance beyond the definition it adopted more than 20 years ago regarding the meaning or use of that term.

LEGAL STANDARD

When a court determines that primary jurisdiction to resolve an issue lies with an agency, a court otherwise having jurisdiction over the case may stay or dismiss the action pending the agency's resolution of the question. *Jackson v. Swift Eckrich, Inc.*, 53 F.3d 1452, 1456 (8th Cir. 1995). The doctrine, and resulting stay, is to be "invoked sparingly, as it often results in added expense and delay." *Red Lake Band of Chippewa Indians v. Barlow*, 846 F.2d 474, 477 (8th Cir. 1988) (internal quotations omitted). In granting a stay in this matter, this Court determined that it was appropriate to defer to the FDA's "'expert and specialized knowledge' in order to attain 'desirable uniformity'" with respect to the use of the terms ECJ and "natural." (Order, Doc. 30, p. 6.) Once the FDA exercises its expert and specialized knowledge, and issues guidance, a stay is no longer necessary. In addition, if it is unclear that the FDA will provide additional guidance, or that it may not do so for an extended period of time, a stay should be lifted. *See Lunde v. Helms*, 898 F.2d 1343, 1345 (8th Cir. 1990) (recognizing that an indefinite stay order can unreasonably delay a plaintiff's right to have his or her case heard and, therefore, is appealable).

ARGUMENT

I. The FDA Has Provided Clarification Regarding the Term ECJ and Has Not Indicated That it Intends to Provide Guidance Regarding the Term "Natural."

A. The FDA Determined that Use of the Term ECJ is False and Misleading.

With respect to ECJ, the FDA concluded its review process on May 25, 2016, and published a revised Guidance for Industry: Ingredients Declared as Evaporated Cane Juice, Doc. No. FDA-2009-D-0430 ("2016 Final Guidance"). A true and correct copy of the 2016 Final Guidance is attached as Exhibit A. Because the Court stayed this case in part based on the FDA's statement that it intended to provide final guidance on the term ECJ by the end of 2016, and the FDA has now provided such guidance, the stay should be lifted. *See* Doc. 30, at p. 6.

Plaintiff's position regarding the FDA's policy on the use of the term ECJ proved to be correct—it is false and misleading. In the 2016 Final Guidance, the FDA reiterated its 16-year old policy that "the term 'evaporated cane juice' is not the common or usual name of any type of sweetener" and that the ingredient should "be declared on food labels as 'sugar,' preceded by one or more truthful, non-misleading descriptors if the manufacturer so chooses (e.g. 'cane sugar')." Ex. A at 4, 6. The FDA advised that "the term 'evaporated cane juice' describes neither the basic nature of the food nor its characterizing properties, and therefore does not comply with 21 CFR 102.5(a)," and stated that "the common or usual name for the ingredient currently labeled as 'evaporated cane juice" includes the term 'sugar' and does not include the term 'juice.'" *Id.* at 6-7. The 2016 Final Guidance reiterates what the FDA has been saying since 2000—use of the term ECJ is unlawful because it violates the "common or usual name" requirement in 21 C.F.R. § 101.4, and the requirement in 21 C.F.R. § 184.1854 that sucrose be referred to as "sugar" on food ingredient labels. In addition, ingredient lists identifying sweeteners derived from sugars such as ECJ are "false and misleading under section 403(a)(1) of the Federal Food Drug and Cosmetics Act (the "FDCA") (21 U.S.C. 343(A)(1)), because they do not accurately describe the basic nature of the food and its characterizing

properties (i.e., that the ingredients are sugars or syrups as required by 21 CFR 102.5)." Ex. A at 7.

Thus, because the FDA has issued its final guidance regarding the use of the term ECJ, Plaintiff respectfully requests that the Court lift the stay and re-open this case.

B. The FDA May Not Provide Additional Guidance Beyond the Existing Definition of "Natural," or May Not Provide It For Several Years.

The FDA's position on the term "natural" has not changed in 23 years, nor has the FDA indicated that it will change its position regarding the use of that term in products containing artificial, and non "natural," ingredients, such as Defendant's almond milk. The FDA's November, 2015 notice opening the comment period regarding the term "natural" does not indicate an intent to revisit its long-standing position that food with an "all natural" label may not include artificial or synthetic ingredients that one would not normally expect to be in the food. *See* 58 FR 2302, Jan. 6, 1993. Indeed, in opening the comment period, the FDA reiterated its "longstanding policy" that a product is not natural if it contains color, artificial flavors, or synthetic substances. *See http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm,* attached hereto as Exhibit B.

Further, although the FDA sought public comment on the use of the term "natural," one of the issues on which it solicited comments was whether it is even appropriate for the FDA to define the term "natural." *Id.* The FDA has also previously admitted that, even if it opens an issue for public comment, there is no guarantee that it would "revoke, amend, or add to the current policy, or develop any definition at all." *See* Letter dated Jan. 26, 2014, from the FDA to three federal judges indicating that no guidance was forthcoming, attached hereto as Exhibit C. As such, guidance from the FDA on the issue is not imminent and, may, in fact, never be provided. At least one court has recognized that "[i]t would be impractical to stay or dismiss [a] case without any assurances that [the] FDA plans to define the term 'natural' as it pertains to food labeling." *Aguiar v. Merisant Co.*, No. 14–00670–RGK–AGR, 2014 WL 6492220, at *8 (C.D. Cal. Mar. 24, 2014).

Even if the FDA were to issue guidance, it has stated that, on average, it takes between 425 and 797 days to finalize guidance documents issued by the agency. *See FDA Withdraws 47 'Outdated' Guidance Documents*, http://www.raps.org/Regulatory-Focus/News/2015/05/05/22102/FDA-Withdraws-47-Outdated-Guidance-Documents/ (last visited Sept. 9, 2016) attached hereto as Exhibit D. Therefore, were the FDA to provide additional guidance, it is likely that it will not do so for several years. Such a delay would prejudice Plaintiff and putative class members, as well as cause additional expense and delay. Plaintiff has made claims for violations of the MMPA and for unjust enrichment based on Defendant's false and misleading product labels on its Almond Milk. If the stay is not lifted, consumers will continue to be misled by Defendant's deceptive labels; and Defendant will continue to be unjustly enriched.

Several courts have lifted similar stays based on the FDA's assertion that additional guidance regarding the use of the term "natural" may never come. *See Cox v. Gruma Corp.*, No. 12-CV-6502 (N.D. Cal. Jan. 10, 2014) (Order (Doc. 71) lifting stay and asking for briefing regarding the primary jurisdiction doctrine in light of the FDA's letter); *see also Barnes v. Campbell Soup Co.*, No. 12-CV-05185 (N.D. Cal. Jan. 24, 2014) (Order (Doc. 58) stating the same same). Because additional guidance regarding the use of the term "natural" may not be forthcoming, Plaintiff respectfully requests that this Court lift the stay. *See Aguiar*, 2014 WL 6492220, at *8.

CONCLUSION

For the foregoing reasons, Plaintiff respectfully requests that this Court re-open the case and lift the stay imposed by this Court's April 14, 2016 Order, and for such other relief as the Court may deem appropriate.

Dated: September 12, 2016

Respectfully submitted,

/s/ Julie E. Piper-Kitchin
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CERTIFICATE OF SERVICE

I hereby certify that on September 12, 2016, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which electronically delivered a copy of the same to all counsel of record.

/s/ Julie E. Piper-Kitchin_____